

SM



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,030	07/06/2001	Naganori Numao	21776/0061	6056

7590 03/16/2004

Connolly Bove Lodge & Hutz LLP  
Suite 800  
1990 M Street, N.W.  
Washington, DC 20036-3425

EXAMINER

LY, CHEYNE D

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 03/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

45

**Office Action Summary****Application No.**

09/899,030

**Applicant(s)**

NUMAO, NAGANORI

**Examiner**

Cheyne D Ly

**Art Unit**

1631

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-3 and 11-13, drawn to a method for predicting biological functional activity and/or binding activity of a protein, classified in class 702, subclass 19. If this Group is elected, then the below summarized 2 species sets (A and B), election of a species from each set is required.
  - II. Claims 4 and 11-13, drawn to a method for predicting biological functional activity and/or binding activity of a nucleotide sequence, classified in class 702, subclass 20. If this Group is elected, then the below summarized 1 species set (A), election of a species from each set is required.
  - III. Claims 5-13, drawn to a method for predicting biological functional activity and/or binding activity of an amino acid and other nucleotide sequence, classified in class 702, subclasses 19 and 20. If this Group is elected, then the below summarized 3 species sets (A and B), election of a species from each set is required.
  - IV. Claim 14, drawn to a binding mode of at least two kinds of proteins or nucleotides, classified in class 702, subclasses 19 and 20. If this Group is elected, then the below summarized 3 species sets (A and B), election of a species from each set is required.
  - V. Claim 15, drawn to an application of biological functional activity of a protein or nucleotide sequence, classified in class 702, subclasses 19 and 20. If this Group

Art Unit: 1631

is elected, then the below summarized 4 species sets (A-C), election of a species from each set is required.

2. Claims 11-13 link(s) inventions of Groups I, II, and III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 11-13. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### **SPECIE ELECTION REQUIREMENT**

3. This application contains claims directed to the following patentably distinct species of the claimed invention:

#### **FOR ALL GROUPS:**

##### Species (A):

4. Species of natural-type or non-natural-type are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select a natural-type or non-natural-type.

Art Unit: 1631

5. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-15 are generic to the above species in all Groups.

**FOR GROUPS I and III-V:**

Species (B):

6. Species of motifs are cited in claims 2 and 6, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select an unspecified type of motif or a type of motif from those listed in claims 2 and 6.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3 and 5-13 are generic to the above species.

**FOR GROUP V**

Species (C):

7. Species of employment for activities are cited in claim 15, which are generally separately analyzed and published, and thus document the undue search burden if searched together. Thus, applicants are required to select a type of employment activity from those listed in claim 15.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 15 is generic to the above species.

Art Unit: 1631

9. Applicant is advised that a reply to this requirement must include an identification of a specie from list of specie sets cited above that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. The inventions of Groups I-III are distinct inventions because they are directed to different methods regarding the critical limitations therein. For Group I, the critical feature is a method for predicting biological functional activity and/or binding activity of a protein. For Group II, the critical feature is a method for predicting biological functional activity and/or binding activity of a nucleotide sequence. For Group III, the critical feature is a method for predicting biological functional activity and/or binding activity of an amino acid and other

Art Unit: 1631

nucleotide sequence. The completely distinct critical features of each Group support the undue search burden if they were examined together.

13. Inventions of Group IV and [I-III] are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

In the instant application, the binding mode of Group IV may be generated by any of the methods of Groups I-III, or alternatively, by using X-ray crystal structure data. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

14. Inventions V and [I-III] are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

In the instant application, the activity of Group V may be generated by any of the methods of Groups I-III, or alternatively, by using X-ray crystal structure data. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

Art Unit: 1631

15. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

16. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

17. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

18. 2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

19. 3. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

20. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

C. Dune Ly  
3/11/04

  
ARDIN H. MARSCHER 3/15/04  
PRIMARY EXAMINER